REMARKS

The courtesy extended by Examiner Sznaidman to applicants' attorney, Robert G. Mukai, during the telephonic interview on January 25, 2011, is greatly appreciated. During the interview, an explanation of the present invention was presented including references to various passages within the specification. The draft claims previously sent to Examiner Sznaidman on January 24, 2011, were discussed and the basis for certain claim terminology was explained, including the support for the term "consisting essentially of" and the recitation of seeds of the cereal. The prior art cited in the Official Action was next discussed and the reasons why the amended claims were patentable thereover were presented. In this regard, it was pointed out that the Pirgozliev et al. publication taught away from the present invention and also did not in any way disclose the claimed phosphorous compounds as correctly noted in the Official Action. It was then explained that Staub et al., U.S. Patent No. 4,849,219, required the combination of a defined microbicidal acylaniline derivative and phosphorous acid or a salt thereof. It was pointed out that the amended claims exclude the required microbicidal acylaniline derivative as disclosed in Staub et al.

At the conclusion of the interview, Examiner Sznaidman stated that he understood the arguments which were presented and requested that the proposed claims and the arguments be formally submitted in a response to the Official Action.

By the present Amendment, the claims discussed at the interview have been formally presented. More specifically, independent claims 11 and 31 now recite a method for reducing mycotoxin contamination in a cereal consisting essentially of a step of applying at least one compound effective for inhibiting production of

mycotoxin by plant pathogenic fungi of cereals selected from the defined group of phosphorous compounds (potassium phosphite in claim 31) and optionally at least one fungicidal active ingredient for agri-horticultural selected from a further defined group to a seed or plant of a cereal in an amount sufficient for inhibiting mycotoxin production from plant pathogenic fungi in a cereal. The term "consisting essentially of" is supported by the specification such as on page 6, lines 5-20 of the specification (i.e., the corrected translation of PCT application filed on July 15, 2009). This section of the specification describes one embodiment as being a method of reducing the contamination amount of mycotoxin using the defined phosphorous compounds and an embodiment wherein the method of reducing a contamination amount of mycotoxin in cereals involves the previously defined group of phosphorous compounds and one or more fungicidal active components for agri-horticulture referred to as compound B. These later compounds are discussed in greater detail such as in the paragraph beginning at page 7, line 24 and the particular fungicides recited in original claim 7 which are the same fungicides now recited in claims 11 and 31. It is further noted that all of the illustrative examples use the phosphorus compound alone or in combination with one or more of the fungicidal active components recited in claims 11 and 31.

The additional reference to a seed in claims11 and 31 is based on the description in the specification and particularly Examples 5 and 6 which both treat seeds that are then cultured and the wheat grains tested. New dependent claims 36-39 define the method with respect to a seed or plant.

As discussed at the interview and reflected in each of the independent claims of record, the present invention relates to a method for reducing mycotoxin

contamination in a cereal. This method is different from a fungicidal method wherein the goal is to kill pathogenic fungi, particularly the fungi causing Fusarium head blight. Various passages throughout the specification confirm this understanding. For instance, page 7, lines 20-23 states that the defined phosphorous salts "have an excellent inhibitory effect on the mycotoxin contamination, particularly DON contamination, independently on controlling of the pathogenic fungi of the cereals." Similarly, the passage starting at page 12, line 19 states: "This way, it is obvious that giving potassium phosphite reduces the DON contamination concentration in the wheat regardless [of] the presence or absence or the degree of the disease with Fusarium heat blight of cereals..." Further, in the passage beginning at page 19, line 24, the specification explains: "It is obvious that application of potassium phosphite has a high inhibitory effect on the DON production regardless of the presence or absence or the proliferation degree of the fungi for the Fusarium head blight of cereals." Finally, in the passage beginning at page 21, line 8, the specification provides: "It is obvious that the application of potassium phosphite has a high inhibitory effect on the DON production regardless of the presence or absence or the proliferation degree of the fungi for the Fusarium head blight of cereals."

The technical evidence provided in the specification supports the understanding provided in the above quoted portions of the specification. For example, Table 1 on page 10 shows the effect of various treatments on DON (deoxynivalenol) concentration and the incidence rate of Fusarium head blight. Upon considering sections 4 and 7, it can be understood that treatment with potassium phosphite alone, the incidence rate of Fusarium head blight is 1.2 percent, but the DON concentration is 0.69 ppm. On the other hand, in section 7

where no potassium phosphite is applied, but conventional fungicidal control is used (which uses **multiple** applications of **combinations** of conventional applications as described on page 8), the incidence rate of Fusarium head blight is only 0.9 percent, but the DON concentration is 6.16 ppm which is well above the 1.1 ppm standard value identified in the paragraph below Table 1. Section 3 can also be compared with section 7 where it can be observed that the application of potassium phosphite in addition to conventional fungicidal control significantly reduces the DON concentration, but the incidence rate of Fusarium head blight is the same.

Other technical data provided in the specification can lead to a similar understanding. With regard to Example 6 on page 20 wherein wheat seeds are soaked in water solutions containing various concentrations of potassium phosphite, the results in Table 6 show that increasing the amount of potassium phosphite results in a decreased amount of DON production, but the amount of Fusarium head blight pathogenic fungus is about the same except at a treatment concentration of 2.800 percent.

Based on the foregoing discussion and the technical data provided in the specification, those of ordinary skill in the art will understand that the claimed method for reducing mycotoxin contamination in a cereal is not the same as a fungicidal method for controlling pathogenic fungi that can cause Fusarium head blight. With this understanding in mind, it is apparent that the claims now of record are patentable over the cited prior art, particularly the Pirgozliev et al. article entitled "Effect of dose rate of azoxystrobin and metconazole on the development of Fusarium head blight and the accumulation of deoxynivalenol (DON) in wheat grain" in view of Staub et al., U.S. Patent No. 4, 849,219. As the title implies, the Pirgozliev

et al. publication reports on studies conducted using various dosages of azoxystrobin and metconazole with respect to the development of Fusarium head blight and the amount of DON. In providing the background of the study, the publication includes the following statement in the last full paragraph in the left column of page 470:

> Fungicidal control of FHB has proved inconsistent and conflicting evidence exists regarding the effect of fungicides on the mycotoxin accumulation in grain contaminated by *Fusarium* species. Results from *in vitro* studies have indicated that the presence of certain fungicides can result in elevated concentrations of *Fusarium* toxins.

With respect to the two fungicides selected for the study, the publication reports in the last paragraph of the left hand column on page 471 that metconazole was included since it was known to be effective at controlling Fusarium head blight while axoxystrobin had been shown to be ineffective against *Fusarium* species and had been observed to increase the concentration of DON in harvested grain.

The results of the study are set forth in the passage beginning in the left hand column of page 472 and in the paragraph bridging the first and second columns of that page wherein it is stated that either metconazole or azoxystrobin reduce significantly the severity of the disease when compared to untreated controls. However, after providing the specific results in Tables 3 and 4 on pages 473 and 474, respectively, the publication states in the left hand column on page 474:

> The lack of any obvious cluster indicates that neither azoxystrobin nor metconazole influenced DON concentration within grain other than by altering the amount of trichothecene-producing *Fusarium* present.

This point is emphasized in the paragraph bridging pages 476 and 477 wherein the publication discloses that fungicides provide a valuable tool for reducing

DON concentration in wheat by reducing the colonisation by trichothecene-producing *Fusarium* species.

It is clear to those of ordinary skill in the art that the Pirgozliev et al. publication merely sets forth the conventional wisdom in the art. That is, in order to control DON contamination, one applies a fungicide, such as azoxystrobin or metconazole, in order to reduce the colonization by *Fusarium* species. As explained above, this is not what the present invention provides which is reflected in the quoted passages from the present specification describing the inhibitory effect on mycotoxin contamination independently of controlling the pathogenic fungi of the cereals and the technical results reported in the specification. Indeed, the quoted passage from the Pirgozliev et al. publication on page 474 reporting that neither azoxystrobin nor metconazole influenced DON concentration other than by altering the amount of fungi present would lead those of ordinary skill in the art away from the substantial advance in the art that applicants have made.

In addition to the complete failure of the Pirgozliev et al. publication to address the challenge met by the present invention, the publication totally fails to disclose or suggest the specific phosphorous compounds defined in the claims of record. This deficiency is acknowledged at the bottom of page 5 of the Official Action. In an attempt to bridge this deficiency, additional reliance has been placed on Staub et al. which provides a microbicidal composition comprising the combination of at least one microbicidal acylaniline derivative and phosphorous acid or a salt thereof in order to obtain a synergistic activity against plant diseases. The specific reasons as to why the defined combination is required are set forth in the patent and particularly in the paragraph beginning at column 3, line 14 which explains that the fungicidal

activity of the mixture of the acylaniline derivative and the phosphorous acid or salt is synergistically enhanced, phytotoxicity is avoided and the combination controls strains of pathogens that are resistant to the acylanilines.

In the passage beginning at the top of column 5, Staub et al. discloses that the combinations are effective against various phytopathogenic fungi and can be applied to many different types of target crops. While Fusarium and cereals are included in the description, none of the working examples are used on a cereal crop to combat Fusarium.

Staub et al. does not seek a reduction of mycotoxin contamination in cereal and instead relates to microbicidal compositions that are effective against a variety of phytopathogenic fungi. As such, the patent would not lead those or ordinary skill in the art to the presently claimed invention and would clearly not lead to any recognition of the substantial advantages which are discussed above and set forth in the present application. Furthermore, while applicants do not concede that the teachings of Staub et al. can be properly combined with those of the Pirgozliev et al. publication, it is indisputable that the patent requires the combination of the defined acylaniline derivative with the phosphorous acid or salt thereof. The claims now of record exclude the presence of the acylaniline derivative as described in the patent and therefore any hypothetical combination of Staub et al. with the Pirgozliev et al. publication would not lead to the invention as defined in the claims of record and most certainly would not lead to a recognition of the surprising results that applicants have been able to obtain in accordance with their invention. In this respect, none of the defined acylaniline derivatives disclosed in Staub et al. meets the defined group of fungicidal active ingredient recited in the claims now record and it is clear that the

inclusion of the acylaniline derivative would have a material effect on any composition that includes the same as expressly taught by the patent itself.

For the reasons provided above, and in view of the claims and evidence of record, applicants respectfully maintain that the claims are patentable in all regards and therefore respectfully request reconsideration and allowance of the present application.

As a final matter, consistent with the discussion at the interview, attached hereto are the issued patents based on the corresponding applications in Europe, Australia and New Zealand.

Should the Examiner wish to discuss any aspect of the present application, he is invited to contact the undersigned attorney at the number provided below.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

Respectfully submitted,

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Date: February 2, 2011